REMARKS

Claims 1-13 currently appear in this application. The Office Action of September 27, 2002, has been carefully studied. These claims define novel and unobvious subject matter under Sections 102 and 103 of 35 U.S.C., and therefore should be allowed. Applicants respectfully request favorable reconsideration, entry of the present amendment, and formal allowance of the claims.

Rejections under 35 U.S.C. 112

Claims 3 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 3 and 4 are said to be indefinite in reciting "p75:FC inhibitor."

This rejection is respectfully traversed. Claims 3 and 4 have been amended to make it clear that the compound that neutralizes the effect of secreted TNF alpha is a compound that inhibits the production of p75:FC.

It is respectfully submitted that the present inventors have discovered that etanercept and infliximab inhibit p75:FC, and that therefore it is not unreasonable to claim a new function for a known compound.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is respectfully traversed. As the Examiner is aware, MPEP Section 2164.01 states that the absence of working examples or lack of evidence that the claimed invention works as described should not be the sole reason for rejecting the claimed invention for lack of enablement. The presence of only one working example should never be the sole reason for rejecting claims as being broader than the enabling disclosure.

In Section 2164.03 of the MPEP, it is stated that even in unpredictable arts, a disclosure of every operable species is not required. In the present case, the inventors have demonstrated that compounds that neutralize the activity of secreted TNF, such as a ligand binding protein of the human p75 TNF receptor linked to the Fc portion of human IgG1, or a humanized monoclonal antibody that neutralizes the activity of TNF, can be used to reverse evidence of hepatic inflammation associated with

active hepatitis, as well as to reduce the viral load by 80%.

Additionally, the inventors have stated in paragraph 0019 that TNF neutralizing compounds were found not only to eliminate the symptoms of rheumatoid arthritis, but were also found to reverse the clinical symptoms associated with hepatitis, including normalization of liver enzymes and decrease in serum viral levels. This is evidence of the successful use of TNF neutralizing compounds in a plurality of patients, even though each incident is not described in the specification in detail. However, the inventors signed a declaration attesting to the fact that all statements made herein of their own knowledge are true; and further that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 81 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon. Therefore, it is respectfully requested that the Examiner give full credence to the evidence presented in the specification.

Art Rejections

Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by The Merck Manual of Diagnosis and Therapy.

This rejection is respectfully traversed. The claims are directed to treating hepatitis by administering to a patient in need thereof an effective amount of a compound that neutralizes the effect of secreted TNF alpha. The specification has demonstrated that compounds which neutralize the effect of secreted TNF alpha are useful for treating hepatitis, both in reducing the viral load and normalizing liver enzymes, as well as boosting the immune system (paragraph 0019). There is absolutely nothing in the Merck Manual that discloses or suggests neutralizing the effect of secreted TNF alpha. While interferon may be used to reduce inflammation in autoimmune hepatitis, there is nothing at all in this reference regarding neutralizing the effects of TNF alpha. The Merck Manual on page 386 specifically states that interferon is used to suppress viral replication, but overall results are relatively disappointing. Since interferon is said to be disappointing in treating viral hepatitis, this reference really teaches away from using interferon to treat hepatitis. There is nothing at all in the Merck Manual that even suggests that interferon treatment neutralizes the effects of TNF alpha.

It is noted that the art made of record and not relied upon is merely considered to be pertinent to applicant's disclosure.

In view of the above, it is respectfully submitted that the claims are now in condition for allowance, and favorable action thereon is earnestly solicited.

Respectfully submitted,

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